



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

|   |           |   |
|---|-----------|---|
| <b>(51) International Patent Classification<sup>4</sup> :</b><br><br><b>B65D 83/14</b>  | <b>A1</b> | <b>(11) International Publication Number:</b> <b>WO 88/ 07010</b><br><br><b>(43) International Publication Date:</b><br>22 September 1988 (22.09.88)  |
| <p><b>(21) International Application Number:</b>      PCT/GB88/00197</p> <p><b>(22) International Filing Date:</b>      11 March 1988 (11.03.88)</p> <p><b>(31) Priority Application Number:</b>      8705965</p> <p><b>(32) Priority Date:</b>      13 March 1987 (13.03.87)</p> <p><b>(33) Priority Country:</b>      GB</p> <p><b>(71) Applicant (for all designated States except US):</b> RIKER LABORATORIES, INC. [US/US]; 19901 Nordhoff Street, Northridge, CA 91324 (US).</p> <p><b>(72) Inventor; and</b><br/> <b>(75) Inventor/Applicant (for US only) :</b> BOLTON, Philip [GB/GB]; 5 Sawley Drive, Great Harwood, Blackburn, Lancashire (GB).</p> <p><b>(74) Agent:</b> BOWMAN, Paul, Alan; Lloyd Wise, Tregear &amp; Co., Norman House, 105-109 Strand, London WC2R 0AE (GB).</p> |           | <p><b>(81) Designated States:</b> AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.</p> <p><b>Published</b><br/> <i>With international search report.</i></p> |
| <p><b>(54) Title:</b> AEROSOL VALVE</p> <div data-bbox="527 1102 1201 1827"> </div> <p><b>(57) Abstract</b></p> <p>A fast-fill, fast-drain, metered dose dispensing valve for use with an aerosol container in which the lower valve seal (16) of the metering chamber (4) is positioned outside the metering chamber to ensure reliable performance and constant dosage volume within the metering chamber.</p>  |           |   |

***FOR THE PURPOSES OF INFORMATION ONLY***

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

|    |                              |    |  |    |                          |
|----|------------------------------|----|--|----|--------------------------|
| AT | Austria                      | FR | France                                   | ML | Mali                     |
| AU | Australia                    | GA | Gabon                                    | MR | Mauritania               |
| BB | Barbados                     | GB | United Kingdom                           | MW | Malawi                   |
| BE | Belgium                      | HU | Hungary                                  | NL | Netherlands              |
| BG | Bulgaria                     | IT | Italy                                    | NO | Norway                   |
| BJ | Benin                        | JP | Japan                                    | RO | Romania                  |
| BR | Brazil                       | KP | Democratic People's Republic<br>of Korea | SD | Sudan                    |
| CF | Central African Republic     | KR | Republic of Korea                        | SE | Sweden                   |
| CG | Congo                        | LI | Liechtenstein                            | SN | Senegal                  |
| CH | Switzerland                  | LK | Sri Lanka                                | SU | Soviet Union             |
| CM | Cameroon                     | LU | Luxembourg                               | TD | Chad                     |
| DE | Germany, Federal Republic of | MC | Monaco                                   | TG | Togo                     |
| DK | Denmark                      | MG | Madagascar                               | US | United States of America |
| FI | Finland                      |    |  |    |                          |

AEROSOL VALVE

This invention relates to a dispensing valve for use with an aerosol container and in particular to a dispensing valve capable of dispensing metered doses of the contents of an aerosol container.

5       The use of aerosol devices to administer drug or other therapeutically active compounds by inhalation therapy is common, particularly for treatment of lung complaints such as asthma. Aerosol dispensing containers are charged with a self-propelling liquid composition  
10       containing the medicament dispersed or dissolved therein and provided with a valve capable of discharging metered amounts of the composition.

Known aerosol dispensers having metering valves designed for inverted operation generally have a metering  
15       chamber and dipcup which retain a fresh charge immediately after a charge previously held in the metering chamber has been dispensed. This feature is incorporated in the valve to avoid the need to prime before use. However, there are a number of disadvantages with this type of arrangement  
20       particularly if the contents are held in the metering chamber for prolonged periods of time.

Prolonged intimate contact of many aerosol formulations intended for oral or nasal administration with the valve rubbers of metering chambers can result in  
25       leaching of components from the rubber mix, which may produce an unacceptable taste or in extreme cases cause the product within the metering chamber to become unstable.

In some known valves there is often loss of contents from the metering chamber on prolonged standing. This may be caused by a number of factors including imperfect valve seals and fluctuations in the temperature and/or vapour pressure.

British Patent Nos. 2004526B and 2086845B disclose metering dispensing valves for inverted operation which do not employ a dipcup arrangement and the metering chamber is drained when the aerosol container is positioned with the valve uppermost. The metering chamber has an opening communicating with the interior of the aerosol container associated with a valve seal which is selectively blocked and exposed by a portion of the valve stem as it is moved from its operative to inoperative positions.

In one arrangement the valve stem has a valve member of larger cross-section thereon, the valve member being arranged to enter the opening and make a sealing fit with the associated valve seal during movement of the stem from its inoperative to its operative position, to remain in a sealing fit when the stem reaches its operative position but to be completely disengaged from the opening when the stem is in the inoperative position and the said opening having an area such that when the valve stem is in the operative position and the valve member is disengaged from the opening material can freely enter or leave the metering chamber under the effect of gravity without the flow of material being significantly impeded and a return spring surrounding the valve member within the metering chamber and arranged to resist movement of the valve stem

to its operative position. The valve seal comprises an annulus positioned within the chamber engaging the periphery of the opening held in place by the return spring.

5       The above arrangement of the valve seal has several potential disadvantages.

Many seals based upon rubber and polymeric materials become swollen and soften upon contact with aerosol propellants. A swollen seal reduces the capacity of the  
10   metering chamber and also may reduce the aperture in the seal preventing free drainage of the contents within the metering chamber when the valve member is disengaged.

The action of the return spring on the seal, particularly if the seal has become softened or swollen,  
15   may cause distortion of the seal causing it to tightly grip the valve member increasing friction the valve and impairing the easy operation of the valve.

The invention provides an improved metering dispensing valve in which these disadvantages are at least  
20   substantially overcome.

According to the present invention, there is provided a valve for dispensing metered doses from an aerosol container when the container is held in an inverted position, the said valve comprising a valve body with an  
25   internal metering chamber which is fixed with respect to the valve body; a valve stem having a valve member thereon, and outlet passage through which a charge can be dispensed from the metering chamber and a transfer port through which the charge can pass from the metering

chamber to the outlet passage when the stem is disposed in an operative position; a first valve seal with which the valve stem is a sliding and sealing fit, the transfer port being so disposed that when the stem is in the inoperative position the charge to be dispensed cannot pass through it from the metering chamber; the metering chamber having an opening associated with a second valve seal through which material to be dispensed can pass when the stem is in the inoperative position, the valve member being constructed and arranged to enter the opening and make a sealing fit with the second valve seal during movement of the stem from its inoperative to its operative position, to remain in a sealing fit when the stem reaches its operative portion but to allow free communication through the opening when the stem is in the inoperative portion, the said opening having an area such that when the valve stem is in the inoperative position the said material can freely enter or leave the metering chamber under the effect of gravity without the flow of material being significantly impeded, and a return spring surrounding the valve member within the metering chamber and arranged to resist movement of the valve stem to its operative position in which the second valve seal is positioned externally of the metering chamber.

25       The metering valve of the invention has the second valve seal positioned outside the metering chamber which has a number of advantages over the use of a seal within the metering chamber.

      The volume of the seal has no effect upon the

capacity of the chamber and accordingly the dimensions of the seal may be selected from a wide range of sizes.

The seal may conveniently be held securely in place by a shroud fitted over the metering chamber thereby  
5 reducing to a minimum the area of the seal which is exposed to the contents of the aerosol and ensuring the seal will not become displaced during movement of the valve stem. The shroud may also perform an additional function of retaining the seal of a pressure filling  
10 valve.

The provision of a seal outside the metering chamber avoids problems associated with direct contact by a valve seal with the return spring.

Preferably the valve stem, metering chamber and  
15 shroud are constructed of metal or plastics material allowing the components to be made to close tolerances.

The valve of the invention does not allow either gas or liquid to be trapped in the metering chamber when the stem is in its inoperative position.

20 Any gas that enters the valve is immediately released and replaced with liquid when the can is inverted. The valve is therefore self-priming and will produce an improved shot weight consistency. When the aerosol is inverted and shaken a free interchange of liquid will  
25 occur between the metering chamber and the can contents.

The need to fit a dipcup to ensure efficient removal of the maximum amount of product from the can is obviated thereby, reducing the overall height of the valve. The result is a very short squat valve which fills the nose of

the ferrule and leaves a negligible amount of product in the can at the end of its life.

In a preferred embodiment of the invention, the valve member is completely disengaged from the second valve seal when the valve stem is in its inoperative position.

In accordance with a further embodiment of the invention the valve member extends through the second valve seal both in the operative and inoperative positions of the valve stem, the end of the valve member extending through the second valve seal having a passage extending from the end and communicating with one or more ports which communicate with the metering chamber only when the valve stem is in its inoperative position thereby allowing material to freely enter or leave the metering chamber.

The invention will now be described with reference to the accompanying drawings in which:

Figure 1 represents a vertical cross-section through a valve in accordance with the invention, and

Figure 2 represents a vertical cross-section through a different valve in accordance with the invention.

Referring to Figure 1 the valve comprises a ferrule or cap 2 intended to be crimped to the neck of an aerosol container. The metering chamber 4 is of constant volume and is fixed with respect to the cap 2. A valve stem 6 extends into the chamber 4 through a first valve seal 8 in sliding sealing engagement with said valve seal. The valve stem 6 has a valve member 10 having a shoulder 12 which makes sealing contact with the valve seal 8 when



the valve stem 6 is in its inoperative position.

The base of the chamber 4 is provided with an opening 14 communicating with the aerosol container (not shown). A second annular valve seal 16 is provided outside the chamber engaging the periphery of the opening 14. The seal 16 is held in place by a shroud 18 fitted over the chamber 4 and provided with an opening 20 aligned with the openings of the seal 16 and chamber. When the valve stem is in its inoperative position (as shown in the drawings) the contents of the aerosol container can pass freely through the opening into the chamber and vice versa.

When the valve stem 5 is moved downwards towards its operative position the valve member 10 engages the second valve seal 16 sealing the opening 14 of the chamber. Further movement of the valve stem maintains the seal and the valve stem will reach its operative position in which the port will communicate with the chamber 4 allowing discharge of the contents therein via passage 24 thereby emptying the chamber of the predetermined volume of contents. The valve stem 5 is biased towards its inoperative position by return spring 26 positioned within the chamber 4 and acting between the shoulder 12 of the valve stem 6 and the base of the chamber.

The valve of the invention may conveniently incorporate a pressure filling valve. The pressure filling valve comprises a port 28 positioned in the side of the chamber 4 towards the top of the chamber and a cylindrical valve seal 30 extending around the outside of the chamber and covering the port 28. The shroud 18 is



provided with a circumferential flange 32 which prevents displacement of the seal 30. The seal 30 is firmly retained between the flange 32 and circumferential flange 34 of the chamber 4. When the aerosol container is filled, the valve stem 6 is depressed to its operative position and the composition is introduced under pressure through the passage 24 in the valve stem 6. The composition flows through port 22 into the chamber 4 and the pressure is sufficient to cause radial displacement of the seal 30 allowing the composition to enter the aerosol container. Vertical displacement of the seal 30 is prevented allowing rapid filling of the container without failure of the pressure filling valve due to vertical displacement of the seal 30.

15       An alternative form of pressure filing valve which may be employed in the valves of the invention is the construction disclosed in British Patent No. 1,287,126 which is incorporated herein by reference. In place of the port 28 and seal 30 such a pressure filling valve  
20 comprises one or more apertures (not shown) in the flange 34, preferably a plurality of radial slots. The apertures or slots are normally sealed by the seal 8. During pressure filling the valve stem 6 is depressed and the composition is introduced through the passage 24 in the  
25 valve stem 6 into the metering chamber. The composition under pressure causes compression of the seal 8 allowing the composition to pass between the seal 8 and the flange 34, through the apertures in the flange 34 into the container.

Figure 2 represents a further valve in accordance with the invention in which identical parts to those in Figure 1 have the same reference numerals. The valve differs from that in Figure 1 in that the valve member 10 extends through the lower seal 16 in both the inoperative and operative positions of the valve stem 6 thereby ensuring correct alignment of the valve stem. The valve member 10 has a passage 40 and one or more apertures 42 which facilitates free flow of material between the metering chamber and container when the valve stem is in its inoperative position. As the valve stem is depressed the aperture 42 is closed by the seal 16 thereby sealing the metering chamber.

## CLAIMS:

1. A valve for dispensing metered doses from an aerosol container when the container is held in an inverted position, the said valve comprising a valve body with an internal metering chamber which is fixed with respect to the valve body; a valve stem having a valve member thereon, and outlet passage through which a charge can be dispensed from the metering chamber and a transfer port through which the charge can pass from the metering chamber to the outlet passage when the stem is disposed in an operative position; a first valve seal with which the valve stem is a sliding and sealing fit, the transfer port being so disposed that when the stem is in the inoperative position the charge to be dispensed cannot pass through it from the metering chamber; the metering chamber having an opening associated with a second valve seal through which material to be dispensed can pass when the stem is in the inoperative position, the valve member being constructed and arranged to enter the opening and make a sealing fit with the second valve seal during movement of the stem from its inoperative to its operative position, to remain in a sealing fit when the stem reaches its operative portion but to allow free communication through the opening when the stem is in the inoperative portion, the said opening having an area such that when the valve stem is in the inoperative position the said material can freely enter or leave the metering chamber under the effect of gravity without the flow of material being

11

significantly impeded, and a return spring surrounding the valve member within the metering chamber and arranged to resist movement of the valve stem to its operative position characterised in that the second valve seal is  
5 positioned externally of the metering chamber.

2. A valve as claimed in Claim 1 characterised in that the valve additionally comprises shroud extending over a portion of the chamber securing said second valve seal.

10

3. A valve as claimed in Claim 1 or Claim 2 characterised in that the valve member is constructed and arranged such that when the stem is in its inoperative position the valve member is completely disengaged from  
15 the second valve seal.

4. A valve as claimed in Claim 1 or Claim 2 characterised in that the valve member extends through the second valve seal both in the operative and  
20 inoperative positions of the valve stem, the end of the valve member extending through the second valve seal having a passage extending from said end and communicating with one or more parts which communicate with the metering chamber only when the valve stem is in its inoperative  
25 position.

5. A valve as claimed in any preceding claim characterised in that the valve additionally comprises a valve means allowing pressure filling through the valve

stem.

6. A valve as claimed in Claim 3 characterised in that the pressure filling means comprises a port in the side of the metering chamber and a cylindrical seal extending around the outside of the chamber and in sealing engagement with said port.

7. A valve as claimed in Claim 6 characterised in that the shroud additionally comprises a circumferential flange abutting said cylindrical seal.

8. A valve as claimed in Claim 5 characterised in that the metering chamber comprises a housing having a circumferential flange in contact with the first valve seal, the circumferential flange having one or more apertures such that when the valve stem is in its operative position and a composition is introduced under pressure through the valve stem the composition under pressure will compress the first valve seal uncovering said aperture in the circumferential flange to cause flow of material from the metering chamber through the aperture into the container.

9. A valve as claimed in any preceding claim characterised in that the valve stem, metering chamber and shroud are composed of metal or plastics material.

1/2

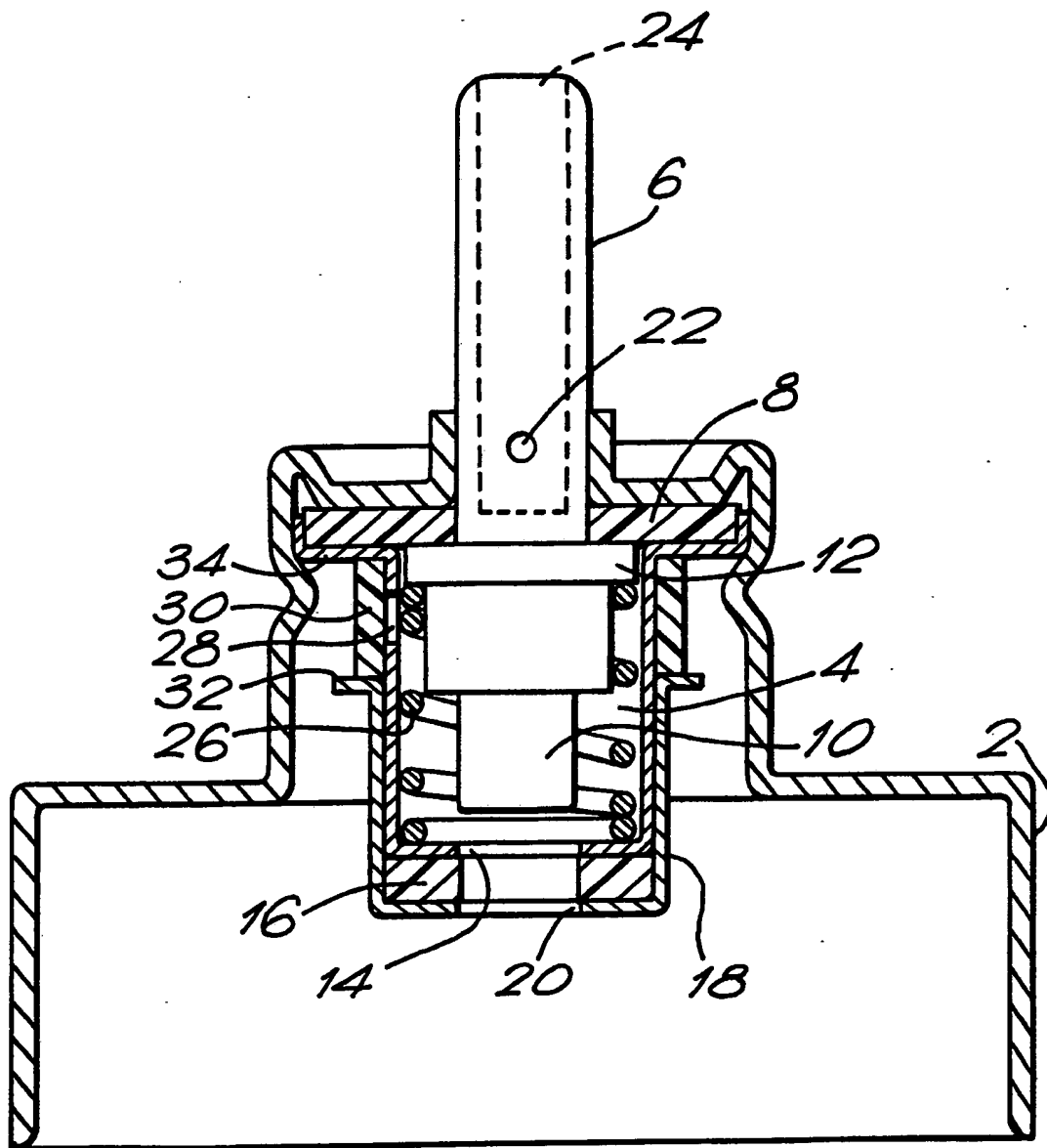


FIG. 1.



2/2

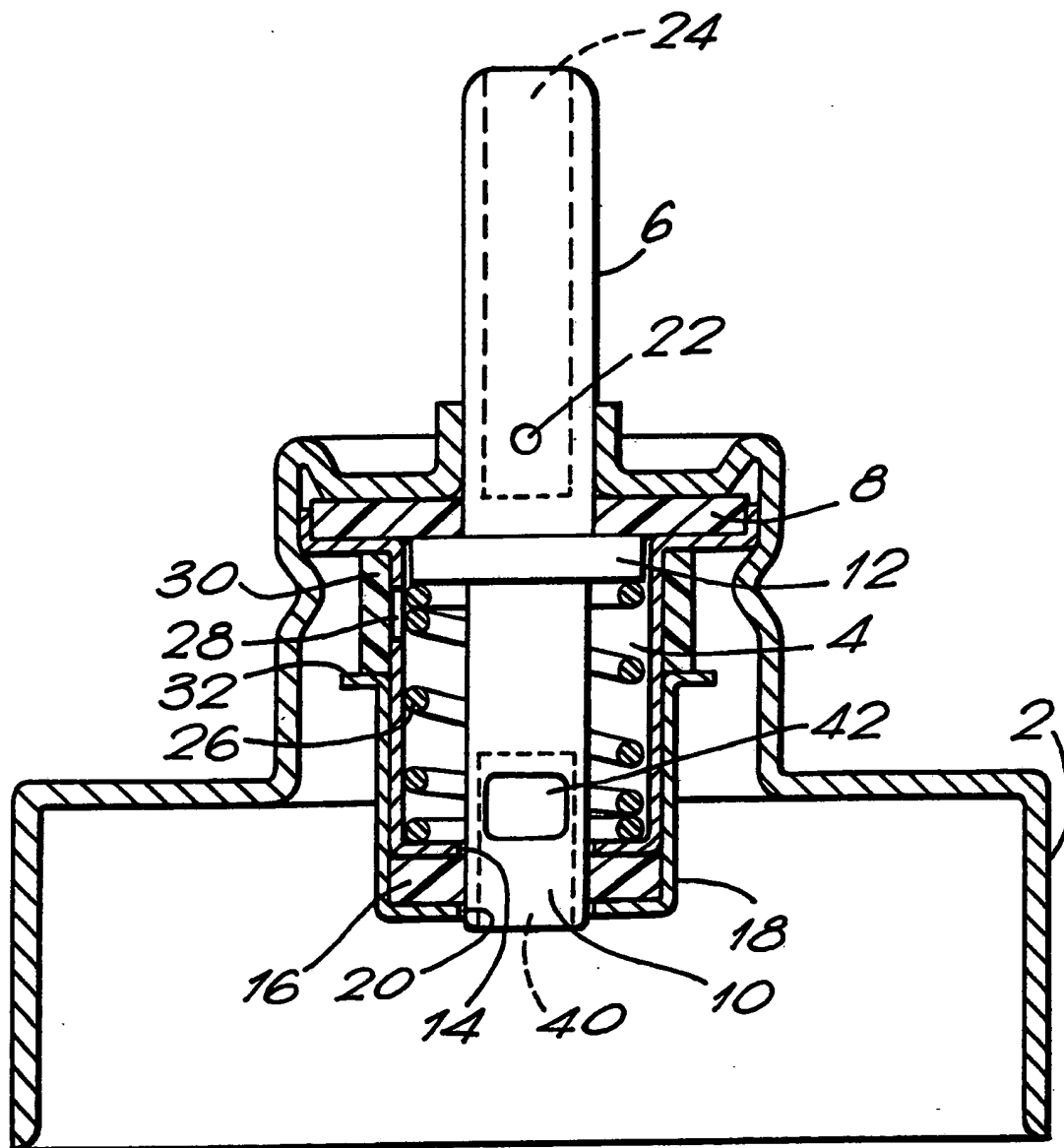


FIG. 2.

**SUBSTITUTE SHEET**

# INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 88/00197

|  |   |                                     |
|--|---|-------------------------------------|
| <b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) <sup>6</sup>  |   |                                     |
| According to International Patent Classification (IPC) or to both National Classification and IPC  |   |                                     |
| IPC <sup>4</sup> : B 65 D 83/14  |   |                                     |
| <b>II. FIELDS SEARCHED</b>   |   |                                     |
| Minimum Documentation Searched <sup>7</sup>  |   |                                     |
| Classification System  | Classification Symbols  |                                     |
| IPC <sup>4</sup>   | B 65 D; G 01 F  |                                     |
| Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>   |   |                                     |
| <b>III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup></b>   |   |                                     |
| Category <sup>10</sup>   | Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>        | Relevant to Claim No. <sup>13</sup> |
| X  | EP, A, 0191614 (BESPAK plc) 20 August 1986, see figures 1-3; page 2, lines 5-21; page 3, lines 11-16; claims 1,6,9,10 | 1,2,4,5,9                           |
| Y  | --  | 3,6,8                               |
| Y  | GB, A, 2086845 (GLAXO GROUP LTD) 19 May 1982 see the whole document cited in the application                          | 3,6                                 |
| A  | --  | 5,7                                 |
| Y  | US, A, 3727806 (K. WILMOT) 17 April 1973, see figures 1,2; column 3, lines 41-57                                      | 8                                   |
| X  | US, A, 2968427 (P. MESHBERG) 17 January 1961 see figures 1,2; column 3, lines 55-75; column 4, lines 32-41            | 1,5,9                               |
| <p><sup>10</sup> Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"d" document member of the same patent family</p> |   |                                     |
| <b>IV. CERTIFICATION</b>   |   |                                     |
| Date of the Actual Completion of the International Search  | Date of Mailing of this International Search Report   |                                     |
| 6th June 1988  | 30 JUN 1988   |                                     |
| International Searching Authority  | Signature of Authorised Officer   |                                     |
| EUROPEAN PATENT OFFICE   | P.E.G. VAN DER PUTTEN   |                                     |

**ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO.**

GB 8800197  
SA 21155

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 17/06/88. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
|---|---------------------|----------------------------|---------------------|
| EP-A- 0191614                             | 20-08-86            | AU-A- 5337586              | 21-08-86            |
|   |                     | JP-A- 61190467             | 25-08-86            |
|   |                     | US-A- 4744495              | 17-05-88            |
| GB-A- 2086845                             | 19-05-82            | GB-A, B 2004526            | 04-04-79            |
|   |                     | FR-A, B 2403833            | 20-04-79            |
|   |                     | JP-A- 54059615             | 14-05-79            |
| US-A- 3727806                             | 17-04-73            | None                       |                     |
| US-A- 2968427                             |                     | None                       |                     |